

REMARKS

1. Status of the Claims

Claims 1, 4, 5, 8-21, 24, and 27-35 stand pending. Claims 2-3, 6-7, 22-23, and 25-26 stand canceled. Claims 1, 4, 5, 15-18, 21, 24, 27 and 29-35 stand rejected. Claims 8-14, 19-20, and 28 are withdrawn.

In this response, claims 1, 19, 21, and 29-35 are amended; claims 4-5, 24, and 27 are canceled; and no claim is added. Therefore, claims 1, 8-21, and 28-35 remain pending with claims 8-14, 19-20 and 28 withdrawn.

Support for the foregoing amendments can be found, for example, in at least the following locations in the original disclosure: the original claims and the specification, page 26, line 9 – page 27, line 10.

2. Rejoinder of Withdrawn Claims

Applicants respectfully request rejoinder of the withdrawn method claims upon allowance of the article or compound/composition claims. *See*, MPEP § 821.04. Dependent claims 8-14 and 28 depend from claims 1 or 21, respectively, and claims 19 and 20 incorporate limitations of at least claim 1. Thus, Applicants submit that upon allowance of claims 1, 15-18, 21, and 29-35, withdrawn claims 8-14, 19-20 and 28 should be rejoined and the restriction requirement withdrawn.

3. Rejection of the Claims Under 35 U.S.C. § 103(a)

Claims 1, 4, 5, 15-18, 21, 24, 27 and 29-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 11-290094, English translation, to Kuniaki, et al. (hereafter “*Kuniaki*”) and JP-11-290094, English translation, to Yukihiisa et al. (hereafter “*Yukihiisa*”) and Kleinig, Univ. Heidelberg, 1967, abstract (hereafter “*Kleinig*”). The Office alleges that *Kuniaki* discloses esterification of astaxanthin by esterifying the hydroxyl groups with fatty acids. Specifically, *Kuniaki* discloses astaxanthin dipalmitoyl ester in Examples 1 and 2 and astaxanthin dicaproyl ester in Example 3. The Office admits that *Kuniaki* at least fails to

disclose forming C8 to C10 fatty acid monoesters and using those monoesters in food or cosmetic compositions. *See, e.g.*, p. 4, para. 12 of the Office Action dated 9/2/09. The Office appears to rely on *Yukihisa* for allegedly disclosing astaxanthin fatty acid monoesters used in food and cosmetics. The Office further cites *Kleinig* for allegedly disclosing esterifying astaxanthin with myristic (C14), lauric (C12), and capric (C10) acids. From these references, the Office alleges that one of ordinary skill in the art would reasonably expect that the method of esterification taught in *Yukihisa* could be used to form astaxanthin C8 to C10 fatty acid monoesters.

Further, in the Advisory Action dated March 22, 2010, the Office alleged that the arguments presented in the response filed March 4, 2010 were not persuasive. Specifically, the Office alleges that the fact that esterification is not sufficiently carried out in the process of *Yukihisa*, does not prove that no esterification occurred or that no monoester was formed. Additionally, the Office alleges that Applicants have failed to provide information on the levels of purity so as to ascertain a difference between the claimed product and a product produced by *Yukihisa*.

Applicants respectfully traverse for the reasons previously presented in the response filed March 4, 2010 and for the additional arguments below, which specifically address the comments in the Advisory Action dated March 22, 2010. The claims have been amended to recite that the medium-chain fatty acid has 8 carbon atoms. *Yukihisa* fails to disclose an astaxanthin medium-chain fatty acid monoester having 8 carbon atoms. Further, as asserted previously, the method of producing astaxanthin esters disclosed in *Yukihisa* does not produce the claimed astaxanthin ester, at least because *Yukihisa* fails to, and specifically teaches away from, adding water to the reaction system beyond what was retained by vacuum-dried lipases.

Specifically, *Yukihisa* discloses the following:

Since the reaction in the present invention is a reversible equilibrium reaction, water which generates with progress of the reaction will be a factor which inhibits the reaction. As for the water content at the time of the reaction, 200 ppm to 1000 ppm is desirable in the present invention. When the water content is more than 1000 ppm, main reaction shifts from synthetic reaction to decomposition reaction and the purity of the astaxanthin fatty acid diesters is lowered and

accordingly such a content is not preferable. When the water content is less than 200 ppm, hydration water which lipases have for stability will be removed, leading to inactivation of lipases and accordingly such a content is not preferable.

See, e.g., p. 13, para. 18 of the English Translation.

The water present in the system of *Yukihisa* is not separately added to the system. *See, e.g.,* Examples 1-10 of *Yukihisa*. The water content that is described in *Yukihisa* is obtained from the addition of vacuum-dried lipases into the reaction system, wherein the lipases retain a small amount of water.

Applicants also use similar vacuum-dried lipases with small amounts of water, and then separately adds additional water to the reaction system to produce astaxanthin medium chain fatty acid monoester with the medium chain having 8 carbon atoms. In particular in Table 1 on page 8 of the instant Specification, 0 water % refers to no separately added water in the system, but it does include small amounts of water added only with the dried enzyme. Thus, the water content in a reaction system of *Yukihisa*, where no separately added water is present, corresponds to the reaction system of 0 water % condition in Table 1 on page 8 of the instant Specification. *See, e.g.,* p. 8, l. 5-20. The results of 0 water % condition in Table 1 shows that the method, which is similar to *Yukihisa*, produces no detectable amount of astaxanthin octanoic acid monoester. *See, e.g.,* p. 8, ll. 17-20. In contrast to the Office's allegation, the instant specification provides sufficient evidence that no astaxanthin octanoic acid monoester was formed or could have been formed by the process of *Yukihisa*.

Further, the Office alleges that the description in the instant specification that "in the method of the prior technique (i.e. *Yukihisa*), if a medium-chain fatty acid is used instead of a long chain fatty acid, esterification is not sufficiently carried out" does not prove that no esterification occurred. However, the Office has misinterpreted the description of the instant specification. Lipase reactions are reversible, when the esterification reaction and hydrolysis reaction are carried out simultaneously. When medium chain fatty acids are used, especially octanoic fatty acid, as substrates in the method of *Yukihisa*, the hydrolysis reaction occurs predominantly, while the esterification is not sufficiently carried out. Thus, no astaxanthin medium chain fatty acid monoester is formed in the reaction system of *Yukihisa*, at least because

“esterification . . . not sufficiently carried out” means that esterification is not sufficiently carried out to form astaxanthin medium chain fatty acid monoester in a reaction system. Therefore, for at least the above reasons, the method of *Yukihisa* cannot produce astaxanthin medium chain fatty acid monoester having 8 carbon atoms. Additionally, *Yukihisa* specifically teaches away from adding water to the reaction system, which is a modification to the method of *Yukihisa* that is needed to produce astaxanthin medium chain fatty acid monoester having 8 carbon atoms.

Additionally, at least because no astaxanthin medium chain fatty acid monoester having 8 carbon atoms is produced in the method of *Yukihisa*, the allegation that Applicant has not provided information on the levels of purity is moot. Applicants do not need to provide information on the levels of purity to distinguish from *Yukihisa*, at least because *Yukihisa* produces no astaxanthin medium chain fatty acid monoester having 8 carbon atoms at any purity level.

Therefore, for at least the above reasons and the reasons previously provided in the response filed March 4, 2010, no *prima facie* case of obviousness has been established. Dependent claims 8-18, 20, and 28-35, which depend from claims 1, 19, or 21, respectively, are also not obvious for at least the reasons for claims 1, 19, and 21. For at least these reasons the rejection should be withdrawn.

CONCLUSION

Should the Examiner have any questions or comments regarding Applicants' amendments or response, she is asked to contact Applicants' undersigned representative at (202) 842-8821. Please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, including for Notice of Appeal, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573 and treat this paper as a Notice of Appeal. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully submitted,
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